

EXPEDITED REVIEW STANDARD OPERATING PROCEDURE

For Institutional Review Board Committee for the Protection of Human Subjects

CPHS/SOP 003/2009

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**EXPEDITED REVIEW STANDARD OPERATING PROCEDURE
REVISION LOG**

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Expedited Review Standard Operating Procedures

I. Federal Regulations

In 1998, the Department of Health and Human Services (DHHS 45 CFR 46.110) and Food and Drug Administration (FDA 21 CFR 56.110) regulations were revised with regard to categories of research that may be reviewed by an expedited review procedure. The list of research categories eligible for an expedited review was expanded and clarified.

The following two criteria must be met before a protocol may be considered for an expedited review process:

1. The activity must present no more than minimal risk to subjects. The regulatory definition of “minimal risk” is the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
2. The protocol procedures must be listed as one of the categories in the regulations’ list of procedures that qualify for an expedited review process. The Research Categories that may qualify for an expedited review process are listed below. Additional information may be found at <http://www.hhs.gov/ohrp/policy/index.html> or www.clinicalresearchresources.com.

The investigator must be aware of the following information regarding expedited research:

1. The categories in the expedited research list apply regardless of the age of subjects, except as noted.
2. The Expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects in terms of financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
3. The expedited review procedure may not be used for classified research involving human subjects.
4. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review -- expedited or convened – utilized by the IRB.
5. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

II. Research Categories Eligible for Expedited Review

Please review research categories to make sure the research is eligible for the Expedited Review before submitting an application. The categories eligible for an expedited review include:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met:
 - (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - (b) from other adults and children, consider the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
 - (a) hair and nail clippings in a nondisfiguring manner;
 - (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
 - (c) permanent teeth if routine patient care indicates a need for extraction;
 - (d) excreta and external secretions (including sweat);
 - (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
 - (f) placenta removed at delivery;
 - (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
 - (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
 - (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

- (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:
- (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
 - (b) weighing or testing sensory acuity;
 - (c) magnetic resonance imaging;
 - (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
 - (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101](#)(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
- (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - (b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Research approved initially through a convened process may reach a stage which qualifies for an expedited review process. This may occur when any of the following are true:

- A reviewer using the expedited procedure determines that the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects. Such determinations of the review will be documented on the expedited review form;
- A reviewer using the expedited procedure determines that the remaining research activities are limited to data analysis. Such determinations of the review will be documented on the expedited review form;
- The convened IRB determines that the research involves no greater than minimal risk and no additional risks have been identified. Such determinations of the IRB will be documented in the meeting minutes.
- A list of all actions taken through an expedited review process will be provided to the IRB at a convened meeting. Any member of the IRB may request re-review of research approved using an expedited process. If such a request is made, the project will be scheduled for convened meeting discussion.

Expedited Review Eligibility – Continuing Review

Continuing review of protocols may be conducted via an Expedited review process if it meets one of the following criteria:

1. Continuing research activities pose no more than minimal risk to subjects, as assessed by the reviewer, AND research met the criteria for initial Expedited review and continues to meet those criteria, AND all procedures continue to meet one or more of the Expedited review categories.
2. Research which was previously reviewed by the convened IRB, but meets the criteria for Expedited review and meets category 8(a), 8(b), or 8(c) for Expedited review as defined by OHRP and the FDA (<http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>).
3. Research which was previously reviewed by the convened IRB, but meets the criteria for Expedited review and meets category 9 for Expedited review as defined by OHRP and the FDA (<http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>).

Expedited Review Eligibility – Modifications to an Approved Protocol

A. An IRB may use the Expedited review procedure to review minor changes in previously approved research during the period (of one year or less) for which approval is authorized [45 CFR 46.110(b)(2)].

B. Modifications to protocols previously approved by a convened IRB may be reviewed via an Expedited review process if they meet the following criteria:

1. Modifications do not pose an increased risk to subjects; AND
2. Modifications constitute a minor change to previously approved research.
3. All added procedures fall within Categories of research that may be reviewed using the expedited procedure (see above Section II. Research Categories Eligible for Expedited Review).

C. Modifications to protocols previously approved by the Expedited review process may be reviewed via Expedited review if they meet the following criteria:

1. With the modifications, the research continues to pose no more than minimal risk to subjects.
2. The modifications do not involve any procedures that do not meet Expedited categories 1 through 7.

D. Examples of changes to previously approved protocols that generally CAN be reviewed by Expedited review procedures:

1. Administrative changes
2. Minor consent form changes
3. Minor changes to recruitment procedures, recruitment materials or submission of new recruitment materials to be used in accordance with approved recruitment methods
4. Minor changes to study documents such as surveys, questionnaires or brochures
5. New study documents to be distributed to or seen by subjects that are similar in substance to those previously approved
6. Changes in payment to subjects or the amount subjects are paid or compensated that are not significant enough to affect the risk/benefit ratio of the study
7. Decrease in the number and volume of sample collections as long as they do not negatively alter the risk/benefit ratio of the study
8. Editorial changes that clarify but do not alter the existing meaning of a document
9. Addition of or changes in study personnel
10. Addition of a new study site
11. Translations of materials already reviewed and approved by an IRB

E. Examples of changes to previously approved protocols that generally CANNOT be reviewed by Expedited review procedures:

1. Changes that adversely affect the risk/benefit ratio of the study or specifically increase the risk to subjects

2. Changes in inclusion/exclusion criteria that impact the risk/benefit ratio of the study
3. Significant changes in study design, such as the addition of a new subject population or the elimination of a study arm
4. New risk information that is substantial or adversely affects the risk/benefit ratio of the study
5. Significant changes to the study documents to be distributed to or seen by subjects
6. New study documents to be distributed to or seen by subjects that include information or questions that are substantively different from materials already approved by the IRB.

III. Review Procedure

The IRB Administrator conducts a pre-review of a protocol to determine submission qualifies for Expedited Review. An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson in accordance with the requirements set forth in 45 CFR 46.110. All of the specified criteria must be satisfied.

The expedited review process is conducted at an IRB expedited review session. The application is reviewed in consultation with the Chair who shall make the final determination of whether the submission meets the eligibility criteria and falls into one or more of the categories allowing review under the Expedited procedure.

For the review of a modification to previously approved research, the reviewer determines that the modification represents a minor change. A change is minor if it does not represent a material change in the research, i.e., (a) the change does not adversely alter the overall risk benefit ratio; (b) the change will not potentially adversely affect the willingness of current participants to remain in the study or the willingness of potential participants to enroll in the study; (c) the change will not diminish the scientific validity of the study; (d) any added revision or procedure involves no more than minimal risk to subjects, and (e) any added procedure falls into one of the categories of research that can be reviewed using the expedited procedure.

The Chair designates which category of approval will apply to the research. The Chair conducting the expedited review may exercise all of the authorities of the Full Committee IRB review except disapproval. The Chair may refer any protocol for a Full Committee IRB review.

The Chair may make one of the determinations listed below. Approvals, concerns and suggestions are communicated to investigators following each step of the review.

- Approval: The submission is approved, and no changes to the submission are recommended.

- **Contingent Approval:** contingent upon the acceptance of requested modifications and/or clarifications: The review stipulates specific clarifications or modifications.
- **Referred for Full committee Review:** The application may be referred for discussion at a convened meeting. Disapproval is an action that may be taken only at a convened meeting.

The agenda for convened meetings is the mechanism by which the IRB members are notified of actions taken using an expedited review process. Expedited review lists are distributed with agendas. Members at the convened meeting may challenge an action taken through the expedited review process and may request that the Expedited procedure be reviewed by the IRB in accordance with non-expedited procedures. A vote of the members shall be taken concerning the request and the majority shall decide.

IV. Documentation of Expedited Review

When a project receives approval or contingent approval through an expedited review process, written notification is provided to the principal investigator. The notice will state the period of approval. No protocol changes, consent form changes, amendments, or addenda may be made to the application without re-review and approval.

The IRB Administrator provides a notification letter of the review outcome to the PI. This notification is consistent with approval notification for full committee review. IRB members are informed of all research activities approved using the expedited procedure by way of the report of expedited review activities at the monthly Board meeting distributed with the agenda and meeting materials.

V. Record Retention

All JSC IRB records associated with specific research proposals are retained indefinitely. An off site storage facility shall be used to store archived materials. All records shall be accessible and available for inspection by authorized agency personnel at reasonable times in a reasonable manner. Documentation and Record Retention Standard Operating Procedure (CPHS/SOP 001/2009) may be consulted for more information.

Regulations:

21 CFR 56.110
21 CFR 312
21 CFR 812
45 CFR 46.110

References:

OHRP guidance on the Use of Expedited Review Procedures (August 11, 2003)
<http://www.hhs.gov/ohrp/humansubjects/guidance/exprev.htm>

OHRP Guidance on Continuing Review, January 15, 2007.
<http://www.hhs.gov/ohrp/humansubjects/guidance/contrev0107.pdf>

63 FR 60364-60367: —Categories of Research that may be reviewed by an Institutional Review Board (IRB) Through an Expedited Review□ (November 9, 1998)

OHRP Human Subject Regulation Decision Charts
(<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>)

NASA Policy Directive (NPD)
7100.8E

NASA Procedural Requirement (NPR)
7100.1

<http://irb.jhmi.edu/Guidelines/expeditedreview.html>

<http://www.research.ucsf.edu/chr/guide/chrExRevCat.asp>

<http://www.oprs.ucla.edu/human/about-IRBs>

<http://www.oprs.ucla.edu/human/documents/pdf/8.pdf>

<http://www.nih.gov/sigs/bioethics/>

Public Responsibility in Medicine and Research <http://www.primr.org/> - addresses a broad range of issues in biomedical and behavioral research, clinical practice, ethics, and the law.